09/928139

Cofe

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Doran R. Pace, Patent Attorney

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR 1.322
Docket No. GJE-136D1
Patent No. 7,164,025

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Marianne Langston, Hooshang Shahriari Zavareh
Issued	:	January 16, 2007
Patent No.	:	7,164,025
For	:	Manufacture of Single Isomer Methylphenidate

Mail Stop Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 CFR 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction (in duplicate) for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below is the column and line number where errors occurred in the patent. In the right-hand column is the page and line number in the application where the correct information appears.

Patent Reads:	**Decision on Appeal dated May 11, 2006, page 2, line 6 of claim 1 reads:**
Column 4, lines 24 and 25:	Page 2, line 6:
"enriched over said d-erythro"	-- enriched over the d-erythro --.

Patent Reads:	**Amendment Under 37 CFR §1.111 dated February 28, 2002, page 2, line 2 of claim 3 reads:**
Column 4, lines 33 and 34:	Page 2 of Amendment, line 2:
"enantiomer with an a chiral carboxylic acid"	--enantiomer with an achiral carboxylic acid--.

A true and correct copy of the Decision on Appeal dated May 11, 2006 and the Amendment dated February 28, 2002 which support Applicants' assertion of the errors on the part of the Patent Office accompanies this Certificate of Correction.

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,

Doran R. Pace
Patent Attorney
Registration No. 38,261
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

DRP/jil
Attachments: copy of the Decision on Appeal dated May 11, 2006
copy of Amendment dated February 28, 2002
Certificate of Correction (in duplicate)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,164,025

APPLICATION NO. : 09/928,139

ISSUE DATE : August 10, 2001

INVENTOR(S) : Marianne Langston, Hooshang Shahriari Zavareh

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4,

Line 24 & 25 "enriched over said d-erythro" should read --enriched over the d-erythro--.

Line 33 & 34, "enantiomer with an a chiral carboxylic acid." should read --enantiomer with an achiral carboxylic acid.--.

MAILING ADDRESS OF SENDER:
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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,164,025

APPLICATION NO. : 09/928,139

ISSUE DATE : August 10, 2001

INVENTOR(S) : Marianne Langston, Hooshang Shahriari Zavareh

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4,

Line 24 & 25 "enriched over said d-erythro" should read --enriched over the d-erythro--.

Line 33 & 34, "enantiomer with an a chiral carboxylic acid." should read --enantiomer with an achiral carboxylic acid.--.

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The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARIANNE LANGSTON
and
HOOSHANG S. ZAVAREH

Appeal No. 2006-0881
Application No. 09/928,139

ON BRIEF

Before GARRIS, PAK, and JEFFREY T. SMITH, Administrative Patent Judges.

GARRIS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal which involves claims 1-8.

The subject matter on appeal relates to a process for obtaining single enantiomer *d-threo* methylphenidate or *l-threo*-methylphenidate, which comprises resolution of a mixture of these enantiomers and racemization of the unwanted enantiomer to give a mixture of all four stereoisomers, wherein the racemization comprises reacting the unwanted enantiomer with an

acid.[1] The resulting mixture is then treated whereby the *threo* stereoisomers are enriched over the *erythro* stereoisomers followed by separation of the *erythro* stereoisomers to leave a mixture of *d-threo*-methylphenidate and *l-threo*-methylphenidate enantiomers for resolution. This appealed subject matter is adequately represented by independent claim 1 (the sole independent claim on appeal) which reads as follows:

1. A process for obtaining single enantiomer *d-threo*-methylphenidate or *l-threo*-methylphenidate, which comprises resolution of a mixture of the *d-threo*-methylphenidate and *l-threo*-methylphenidate enantiomers; racemisation of the unwanted enantiomer, to give a mixture of all four stereoisomers, wherein the racemisation comprises reacting the unwanted enantiomer with an acid; enriching said mixture following racemisation wherein the *d-threo* and *l-threo* stereoisomers of methylphenidate are enriched over the *d-erythro* and *l-erythro* stereoisomers of methylphenidate; and separation of said *d-erythro* and *l-erythro* stereoisomers, to leave the said mixture of *d-threo*-methylphenidate and *l-threo*-methylphenidate enantiomers for resolution.

The references set forth below are relied upon by the examiner in the § 103 and obviousness-type double patenting rejections before us on this appeal[2]:

---

[1] According to the appellants, methylphenidate has two chiral centers, and any compound having two chiral centers will theoretically yield a racemate containing four separate isomers. The appellants further explain that it was known in the prior art to racemize methylphenidate wherein one of the two chiral centers became racemized to thereby yield two isomers (i.e., a mixture of the stereoisomers). However, it is the appellants' position that, prior to their invention, it was not known how to racemize both chiral centers of methylphenidate.

[2] In the answer, the examiner has referred to newly cited references (i.e., the Gao, Beausoleil, and Shimoju references; see pages 6 and 14 of the answer) as supporting her obviousness position even though these references are not included in the examiner's statements of her rejections. If these references are meant to support the proposition that compounds having two chiral centers are theoretically capable of being racemized to yield four isomers as indicated in the paragraph bridging pages 13-14 of the answer, then no such support is necessary particularly since the proposition has not been denied by the appellants (e.g., see the paragraph bridging pages 9 and 10 of the supplemental brief). On the other hand, if these newly cited references are relied upon for supporting the examiner's obviousness conclusions, then the references should have been positively included in the examiner's statements of her rejections. See In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970). Also see the Manual of Patent Examining Procedures (MPEP) § 706.02(j) (Rev. 3, August 2005) and § 2144.08 (id.).

Miller et al. (Miller '261)	4,254,261	Mar. 3, 1981
Zeitlin et al. (Zeitlin)	5,733,756	Mar. 31, 1998
Zavareh	6,121,453	Sep. 19, 2000
Harris et al. (Harris)	US 6,242,464 B1	June 5, 1002

Miller et al. (Miller), "Racemization of 6-oxo-2-piperidine-carboxylic acid enantiomers," Chemical Abstracts 94 :47148 (1981)

Armstrong et al. (Armstrong), "Separation of Drug Stereoisomers by the Formation of ß-Cyclodextrin Inclusion Complexes," Science, Vol. 232, pages 1132-1135 (1986)

Barry et al. (Barry), "Racemization of .alpha.-amino acid esters by aliphatic ketones in the presence of carboxylic acids," Chemical Abstracts 119:73084 (1993)

Claim 1 is rejected under 35 U.S.C.§ 112, first paragraph, "for lack of description and enablement" (answer, page 6).

Claims 1-6 and 8 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Zeitlin or Armstrong in view of the Miller Chemical Abstracts, the Barry Chemical Abstracts or Miller '261.

Claims 1-8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the prior art referred to immediately above and further in view of Harris.

Finally, claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Zavareh '453 in view of the Miller Chemical Abstracts, the Barry Chemical Abstracts, or Miller '261 and further in view of Harris.

(Footnote, continued)
Under these circumstances, it is appropriate to grant the appellants' request on page 6 of the reply brief that these newly cited references not be considered by the Board. It follows that we have not considered and will not further comment upon these newly cited references in our resolution of the subject appeal.

Rather than reiterate the respective positions advocated by the appellants and by the examiner concerning the above-noted rejections, we refer to the supplemental brief and reply brief as well as to the answer for a complete exposition thereof.

OPINION

For the reasons which follow, we cannot sustain any of the rejections advanced on this appeal.

Concerning her § 112 rejection of claim 1, the examiner states that "[t]he [claim 1] limitation of producing all four isomer[s] from the d- or l-threo finds no antecedent basis or enablement" (answer, page 6). Like the appellants, we find the examiner's exposition of this rejection to be less than a model of clarity with respect to why she considers claim 1 (but not the dependent claims) to violate the description and enablement requirements of § 112, first paragraph. The reasons for this lack of clarity are several. For example, the examiner's position is obfuscated by her comparison of appealed claim 1 with the disclosures of appellants' foreign priority documents. These foreign priority disclosures relate to § 119 benefits, not to the description and enablement issues raised by the rejection under review. In any event, for purposes of resolving these issues, we will consider this rejection to be founded upon the examiner's above-quoted criticism concerning the "limitation" of appealed claim 1.

There is no merit in the examiner's belief that the appellants' original disclosure of this application fails to contain written description of the claim 1 process for obtaining single enantiomer *d-threo* methylphenidate or *l-threo*-methylphenidate which comprises racemization of the unwanted enantiomer to give a mixture of all four stereoisomers. This subject matter of

appealed claim 1 was expressly recited in original claim 1 filed with the subject specification, and therefore the appellants' original disclosure would have conveyed with reasonable clarity to those skilled in the art that the appellants had possession on the application filing date of the subject matter in question. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991). Also see MPEP § 2163 et. seq.

The examiner's enablement position also is not well-taken. For example, the disclosure on specification page 4 unquestionably enables the claim 1 process with respect to *d-threo*-methylphenidate. Moreover, as correctly indicated by the appellants, this claimed process is presumptively considered to be enabled with respect to *l-threo*-methylphenidate, and it is the examiner's initial burden to establish a reasonable basis to question enablement. See In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Also see MPEP § 2164 et. seq. On the record of this appeal, the examiner has failed to provide a reasonable explanation as to why the scope of protection provided by claim 1 is not adequately enabled by the appellants' disclosure. Id.

For the above stated reasons, we cannot sustain the examiner's § 112, first paragraph, rejection of claim 1.

Regarding her § 103 rejection of claims 1-6 and 8, the examiner finds that "Zeitline [sic] or Armstrong disclosed all the elements of the claims **except** wherein a recycled by racemization step was not included" but concludes "[i]t would have been prima facie obvious to employ a conventional modification of recycle/racemization step [i.e., see the Miller Chemical Abstracts, the Barry Chemical Abstracts or Miller '261] for the conventional process of Zeitline [sic] or

Armstrong **because** producing higher yields of a desirable single isomer is expected, and such expectation is the attributes taught by the prior art" (answer, page 10).

The examiner's obviousness conclusion is not supported by the here applied prior art. As more thoroughly detailed in the supplemental brief and reply brief, none of the secondary references applied by the examiner contain any teaching or suggestion of racemizing methylphenidate or any similar compound containing two chiral centers and thereby obtaining a mixture of all four stereoisomers (as required by the rejected claims) based upon a reasonable expectation of success. See In re O'Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (obviousness under § 103 requires a reasonable expectation of success).

It follows that the § 103 rejection of claims 1-6 and 8 as being unpatentable over Zeitlin or Armstrong in view of the Miller Chemical Abstracts, the Barry Chemical Abstracts or Miller '261 cannot be sustained.

In discussing her § 103 rejection of claims 1-8, the examiner has made clear that the additionally applied Harris reference is relied upon solely for the limitation of dependent claim 7 (see pages 11 and 13 of the answer). Thus, as applied by the examiner, Harris fails to supply the above-discussed deficiencies of the other applied references. For this reason alone, we cannot sustained the examiner's § 103 rejection of claims 1-8 as being unpatentable over Zeitlin or Armstrong in view of the Miller Chemical Abstracts, the Barry Chemical abstracts or Miller '261 in view of Harris.[3]

[3] As an additional matter of concern regarding this rejection, we observe that the examiner has not even attempted to rebut the appellants' extensive explanation of why the Harris patent should be regarded as disqualified prior art under 35 U.S.C. § 103(c). It was inappropriate for the examiner and for her appeal conferees to have maintained this rejection while failing to proffer any rebuttal whatsoever to the appellants' disqualification argument.

The examiner's obviousness position with respect to the obviousness-type double patenting rejection parallels her obviousness position with respect to the § 103 rejections. Thus, the former rejection is deficient for reasons previously explained with respect to the latter rejections. We also cannot sustain, therefore, the obviousness-type double patenting rejection of claims 1-8 as being unpatentable over claim 1 of Zavareh '453 in view of the Miller Chemical Abstracts, the Barry Chemical Abstracts or Miller '261 in view of Harris.

In conclusion, we have not sustained any of the rejections advanced on this appeal because the examiner has failed to carry her initial burden of establishing a prima facie case of unpatentability with respect to each of these rejections. See In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

ADDITIONAL MATTER

On page 6 of the supplemental brief, the appellants request "acknowledgement of Appellants' claim to foreign priority for both the GB 9602174.6 and GB 9618836.2 British applications under 35 U.S.C. § 119 in the subject '139 application."

The issue of foreign priority benefits is not relevant to any of the rejections before us in this appeal.[4] Therefore, the issue raised by the appellants' afore-quoted request is petitionable rather than appealable. See MPEP § 1201.

Under these circumstances, it would not be appropriate for this panel of the Board to entertain on the merits the request under consideration.

[4] For example, each of the references relied upon by the examiner in her rejections of the independent claim on appeal would be available as prior art regardless of whether the appellants' foreign priority claim is acknowledged or perfected.

SUMMARY

The decision of the examiner is reversed.

Bradley R. Garris
Administrative Patent Judge)
)
)
)
)
Chung K. Pak) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
) INTERFERENCES
)
)
)
Jeffrey T. Smith)
Administrative Patent Judge)

BRG/cam

Saliwanchik, Lloyd & Saliwanchik
A Professional Association
P. O. Box 142950
Gainesville, FL 32614-2950

I hereby certify that this paper is being Facsimile transmitted to the Patent and Trademark Office on February 28, 2002.

Doran R. Pace, Patent Attorney

AMENDMENT UNDER 37 CFR §1.111
Examining Group 1625
Patent Application
Docket No. GJE-136D1
Serial No. 09/928,139

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Ceila Chang
Art Unit	:	1625
Applicants	:	Marianne Langston, Hooshang Shahriari Zavareh
Serial No.	:	09/928,139
Filed	:	August 10, 2001
Conf. No.	:	6929
For	:	Manufacture of Single Isomer Methylphenidate

Assistant Commissioner for Patents
Washington, D.C. 20231

AMENDMENT UNDER 37 CFR §1.111

Sir:

A Petition and Fee for a two-month Extension of Time through and including February 28, 2002, accompanies this Amendment.

In response to the Office Action dated September 28, 2001, please amend the above-identified patent application as follows:

In the Claims

Please substitute the following claims:

Claim 1 (amended):

1. A process for obtaining single enantiomer *d-threo*-methylphenidate or *l-threo*-methylphenidate, which comprises resolution of a mixture of the *d-threo*-methylphenidate and *l-threo*-methylphenidate enantiomers; racemisation of the unwanted enantiomer, to give a mixture of

all four stereoisomers, wherein the racemisation comprises reacting the unwanted enantiomer with an acid; enriching said mixture following racemisation wherein the *d-threo* and *l-threo* stereoisomers of methylphenidate are enriched over said *d-erythro* and *l-erythro* stereoisomers of methylphenidate; and separation of said *d-erythro* and *l-erythro* stereoisomers, to leave the said mixture of *d-threo*-methylphenidate and *l-threo*-methylphenidate enantiomers for resolution.

Claim 3 (amended):

3. The process, according to claim 1, wherein the racemisation comprises heating the unwanted enantiomer with an achiral carboxylic acid.

Please add the following new claim:

8. The process, according to claim 1, wherein the racemisation comprises heating the unwanted enantiomer with a carboxylic acid.

Remarks

Claims 1-7 are pending in the subject application and currently before the Examiner. By this Amendment, Applicants have amended claims 1 and 3 and added new claim 8. Support for the amendments can be found throughout the subject specification, including, for example, at page 3, lines 13-15 and lines 26-27. Entry and consideration of the amendments and new claim presented herein is respectfully requested. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants note that a Claim of Priority Under 35 USC §119 was included with the filing materials when the subject application was mailed to the Patent Office on August 10, 2001. In accordance with MPEP 201.14(b), Applicants reaffirmed their claim to foreign priority and requested that the foreign priority application submitted in the parent application, U.S. application Serial No. 08/792,415, be made of record in the subject application. However, the Office Action Summary page of the instant Action did not include an acknowledgement of Applicants' claim to foreign priority under 35 USC §119 or that the foreign priority documents were received. Accordingly, Applicants respectfully request that their claim to foreign priority be acknowledged and the foreign priority documents be made of record by the Examiner in the subject application.

Claims 1 and 5 are rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner asserts that the recitation in the claims that "racemization proceeds in favor of the *threo* diasteriomer" lacks antecedent basis and an enabling description. In view of this, the Examiner requires removal of the "new matter." Applicants respectfully assert that there is adequate written description in the subject specification and the recitation that "racemization proceeds in favor of the *threo* diasteriomer" does not constitute new matter. However, by this Amendment, Applicants have amended claim 1 to delete reference to the language objected to by the Examiner. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 1-3 and 6 are rejected under 35 USC §103(a) as obvious over Shaflee (1969) in view of Barry (1993) or Miller (1980) and Miller (U.S. Patent No. 4,254,261). In addition, claims 1-6 are

rejected under 35 USC §103(a) as obvious over Shaflee (1969) in view of Barry (1993) or Miller (1980) and Miller (U.S. Patent No. 4,254,261) further in view of Rometsch (U.S. Patent No. 2,957,880). Further, claims 1-7 are rejected under 35 USC §103(a) as obvious over Shaflee (1969) in view of Barry (1993) or Miller (1980) and Miller (U.S. Patent No. 4,254,261) further in view of Rometsch (U.S. Patent No. 2,957,880) and further in view of Jacques (1981) supplemented with Harris (U.S. Patent No. 6,242,464). Applicants respectfully traverse these grounds of rejection.

Applicants respectfully maintain that the claimed invention is not obvious over the cited references, regardless of whether the references are taken alone or in combination. Applicants acknowledge that the Miller and Barry references disclose racemization of a cyclic amino acid (specifically, 6-oxo-2-piperidine-carboxylic acid) and an amino acid ester, respectively. However, as Applicants have indicated in their Amendment dated December 19, 2000 submitted in the parent application (Serial No. 08/792,415), the substrate in the Barry reference has only one chiral center. Similarly, there is only one chiral center in substrate disclosed in the Miller references. These references do not teach or suggest racemization of compounds having two stereogenic centers, such as methylphenidate. As discussed at page 2, lines 8-9, of the subject specification, the subject invention is based on the surprising discovery of means to effect racemization of both chiral centers of methylphenidate. It is only the subject application that teaches means for effectively racemizing a single enantiomer of methylphenidate such that all four stereoisomers are produced.

As during prosecution of the parent application, the Examiner apparently assumes that racemization of any methylphenidate enantiomer will occur at both chiral centers of the molecule so as to produce all four possible stereoisomers. With all due respect to the Examiner, Applicants respectfully assert this assumption is incorrect, as is apparent from the Rometsch patent. Although Example 6 of the Rometsch patent discloses epimerisation with base, only one chiral center of the molecule is racemized with the result that less than all of the four possible stereoisomers are produced. Thus, Applicants respectfully assert that the prior art does not teach or suggest a means for racemization of a single enantiomer of methylphenidate wherein all four stereoisomers of methylphenidate are obtained. Moreover, the prior art teaches away from Applicant's claimed invention in that the Rometsch patent teaches that racemization of methylphenidate occurs at only one of the two chiral centers of the molecule. If the substrate is racemized at only one chiral center,

the product of racemization does not contain the enantiomer that is the specified product of claim 1. This makes the known racemization procedure unsuitable for the recycling process encompassed by claim 1. Applicants respectfully assert that, at the time of the present invention, it was not predictable that they would be able to identify conditions under which all four stereoisomers could be produced from a single enantiomer of methylphenidate.

In addition, Applicants note that the chiral centers of methylphenidate are located on adjacent atoms and are not of a similar type. Consideration of this molecular structure would suggest to the ordinarily skilled artisan that one chiral center can be racemized much more easily than the other, thereby leading to production of fewer than the four possible stereoisomers. This is borne out by the experimental evidence in Rometsch. The effectiveness of Applicants' claimed invention in racemizing methylphenidate is, therefore, surprising. Accoordingly, Applicants respectfully assert that the cited references do not teach or suggest the claimed invention, nor do they provide the requisite reasonable expectation of success in obtaining the invention. Reconsideration and withdrawal of the rejections under 35 USC §103(a) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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DRP/sl
Attachment: Marked-Up Version of Amended Claims

Marked-Up Version of Amended Claims

Claim 1 (amended):

1. A process for obtaining single enantiomer *d-threo*-methylphenidate or *l-threo*-methylphenidate, which comprises resolution of a mixture of the *d-threo*-methylphenidate and *l-threo*-methylphenidate enantiomers; racemisation of the unwanted enantiomer, to give a mixture of all four stereoisomers, wherein the racemisation comprises reacting the unwanted enantiomer with an acid; enriching said mixture following racemisation wherein [the equilibrium of said racemisation proceeds in favor of] the *d-threo* and *l-threo* stereoisomers of methylphenidate are enriched over the *d-erythro* and *l-erythro* stereoisomers of methylphenidate; and separation of [the] said *d-erythro* and *l-erythro* stereoisomers, to leave the said mixture of *d-threo*-methylphenidate and *l-threo*-methylphenidate enantiomers for resolution.

Claim 3 (amended):

3. The process, according to claim 1, wherein the racemisation comprises heating the unwanted enantiomer with an achiral carboxylic acid [a carboxylic acid, wherein said carboxylic acid is achiral].